



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,049	11/28/2001	Jennifer L. Policky	PI-0072 USN	9619

22428 7590 09/22/2005

FOLEY AND LARDNER  
SUITE 500  
3000 K STREET NW  
WASHINGTON, DC 20007

EXAMINER
----------

ULM, JOHN D

ART UNIT	PAPER NUMBER
----------	--------------

1649

DATE MAILED: 09/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/980,049	POLICKY ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	John D. Ulm	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 July 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7,9,11,16,17,19,22,26 and 57-61 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7,9,11,16,17,19,22,26 and 57-61 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>7/13/05</u> .   | 6) <input type="checkbox"/> Other: _____                                    |

Art Unit: 1649

1) Claims 1 to 7, 9, 11, 16, 17, 19, 22, 26 and 57 to 61 are pending in the instant application. Claims 1 to 7, 9, 11, 16, 17, 19, and 22 have been amended, claims 8, 10, 13, 15, 27 and 28 have been canceled and claims 57 to 61 have been added as requested by Applicant in the correspondence filed 13 July of 2005.

2) The amendment filed 13 July of 2005 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

“Please amend the Title of the application as follows:

HUMAN CYSTEINYL LEUKOTRIENE RECEPTORS”

and the claim limitation “wherein the polypeptide has leukotriene receptor activity”.

Applicant is required to cancel the new matter in the reply to this Office Action.

3) Any objection or rejection of record that is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5) Claims 1 to 7, 9, 11, 16, 17, 19, 22, 26 and 57 to 61 are rejected under 35 U.S.C. § 101 because they are drawn to an invention with no apparent or disclosed specific and substantial credible utility for those reasons of record as applied to claims 1 to 7, 9, 11, 13, 15 to 17, 19, 22 and 26 to 28 in section 7 of the previous office action.

Art Unit: 1649

As stated therein, the claimed invention lacks specific and substantial utility in currently available form because instant specification does not identify any ligand for a receptor of the instant invention nor does it identify a specific physiological process which one could reasonably associate with that receptor in light of the evidence of record. To be patentable, an invention must be useful in currently available form. Because the instant specification does not disclose the identity of at least one ligand for a receptor of the instant invention or provide a reasonable basis to support a conclusion that this protein is involved in at least one specific physiological process which one would wish to modulate for clinical effect, the claimed nucleic acid encoding that protein is not useful without further research and inventive contribution.

Applicant has traversed this rejection on the premise that Tables 2 and 3 on pages 81 and 82 of the instant specification "asserts that SEQ ID NO:1 is a cysteinyl leukotriene receptor." Applicant is factually in error. Table 2 of the instant specification expressly states that the probability of SEQ ID NO:1 being a cysteinyl leukotriene receptor is "0". In describing the data presented in Table 2 of the instant specification the text on page 25 therein states that "Column 4 shows the probability score for the match between each polypeptide and its Genbank homolog". With respect to the description of SEQ ID NO:1 in Table 3, the phrase "cysteinyl leukotriene receptor" does not appear. Nowhere in the instant specification, as filed, can one find an express assertion that the amino acid sequence presented in SEQ ID NO:1 therein is the amino acid sequence of a cysteinyl leukotriene receptor.

The fact that SEQ ID NO:1 has subsequently been found to correspond to the amino acid sequence of a cysteinyl leukotriene receptor does not obviate this rejection because the instant specification did not disclose this critical information. An invention must be patentable at the time that an application is filed. Applicant may not rely upon subsequent discoveries to complete the claimed invention. In the decision *In re Lundberg*, 117 USPQ 190, 1958, the CCPA held that "advantages which are not disclosed in application cannot be urged as basis for allowing claims". Further, It is a matter of law that an invention must have a specific and substantial utility "in currently available form", which precludes the need for further research, if that research is needed to establish a utility for the claimed invention (*Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966)),.

6) Claims 1 to 7, 9, 11, 16, 17, 19, 22, 26 and 57 to 61 are rejected under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to use the instant invention for those reasons given above with regard to the rejection of these claims under 35 U.S.C. § 101.

7) Claims 1 to 7, 9, 11, 16, 17, 19, 22, 26 and 57 to 61 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant application as filed did not provide a written description of a polypeptide having the amino acid sequence presented in SEQ ID NO:1 and "cysteinyl leukotriene receptor activity". In fact, the phrase "cysteinyl leukotriene receptor activity"

Art Unit: 1649

is without support in the instant application as filed and a relationship between this activity and SEQ ID NO:1 is a new inventive concept.

8) Claims 1 to 7, 9, 11, 16, 17, 19, 22, 26 and 57 to 61 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by the Takasaki et al. publication (B.B.R.C. 274(2):316-322, 02 Aug. 2000) for those reasons of record as applied to claims 1 to 7, 9, 11, 13, 15 to 17, 19, 22 and 26 in section 12 of the previous office action.

9) Applicant's arguments filed 13 July of 2005 have been fully considered but they are not persuasive.

10) Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 1649

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



JOHN ULM  
PRIMARY EXAMINER  
GROUP 1000